



October 23, 2019

ICU Medical
Yuliya Matlin
Director, Global Regulatory Affairs
600 N. Field Drive
Lake Forest, Illinois 60045

Re: K190157
Trade/Device Name: Diana ChemoClave Transfer Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: ONB
Dated: September 27, 2019
Received: September 30, 2019

Dear Yuliya Matlin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Geeta Pamidimukkala
Acting Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K190157

Device Name

Diana ChemoClave Transfer Set

Indications for Use (Describe)

The Diana ChemoClave Transfer Set is a sterile, single-use closed system transfer device used for drug preparation to transfer drug from a drug vial to an IV bag for intravenous drug administration. It prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

A summary of 510(k) substantial equivalence information in accordance with the requirements of 21 CFR 807.92 for the Diana ChemoClave Transfer Set.

I. SUBMITTER	
Name	ICU Medical, Inc.
Address	600 N. Field Drive, Lake Forest, Illinois 60045, USA
Phone number	(224)-706-2419
Contact Person	Yuliya Matlin, M.S., M.B.A., Director, Global Regulatory Affairs
Date prepared	10/22/2019
II. DEVICE	
Name of Device	Diana ChemoClave Transfer Set (K190157)
Regulation Name	Intravascular Administration Sets, 21 CFR 880.5440
Common Name	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System
Regulatory Class	II
Product Code:	ONB
III. PREDICATE DEVICE	
Predicate – K170110 Diana ChemoLock Transfer Set Reference – K173477 ChemoCLAVE Cytotoxic Medication Preparation and Delivery System (utilized for justifying all components in the system cleared under ONB)	
IV. DEVICE DESCRIPTION	
<p>Diana ChemoClave Transfer Set is intended for use with the Diana Automated Compounding System. It is a disposable, single use ancillary device for Pharmacy Compounding Devices (PCD).</p> <p>The transfer set is comprised of multiple components bonded together to form a single device. These components include the following: stopcock, tubing, ChemoClave, syringe, and cassette handle. When placed in the Diana Automated Compounding System, the Diana ChemoClave Transfer Set allows the transfer of fluids from one container to the other container for reconstitution of lyophilized drug or transfer of stock drug solution to prepare medications. Connections to sourcing/receiving containers are enabled using the dedicated ChemoClave connector.</p> <p>The purpose of this submission is to modify the predicate's Closed System Transfer Device (CSTD) from ChemoLock to ChemoClave, as an alternative to be used with Diana Automated Compounding System.</p>	
V. INDICATIONS FOR USE	
The Diana ChemoClave Transfer Set is a sterile, single-use closed system transfer device used for drug preparation to transfer drug from a drug vial to an IV bag for intravenous drug administration. It prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system.	

VI. COMPARISON OF INTENDED USE WITH THE PREDICATE DEVICE		
	Subject Device	Predicate (K170110)
Feature	Diana ChemoClave Transfer Set	Diana ChemoLock Transfer Set
Intended Use	Same	Same
Indications for Use	The Diana ChemoClave Transfer Set is a sterile, single-use closed system transfer device used for drug preparation to transfer drug from a drug vial to an IV bag for intravenous drug administration. It prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system.	The Diana ChemoLock Transfer Set is a sterile, single-use closed system transfer device used for drug preparation to transfer drug from a drug vial to an IV bag for intravenous drug administration. It prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system.
Classification	Class II	Class II
Product Code	ONB	ONB
Regulation No.	21 CFR 880.5440	21 CFR 880.5440
Use	Single Use	Single Use
Prescription/OTC Use	Prescription Use	Prescription Use
Compatible Set to a particular compounding system	Diana Automated Compounding System	Diana Automated Compounding System
Intended for Direct Connection to Patient During Compounding	No	No
Use Environment for Compounding	Standard Hospital Pharmacy Setting	Standard Hospital Pharmacy Setting
Target Users	Trained health-care personnel	Trained health-care personnel
Closed System Transfer Device (CSTD)	Yes	Yes

Overall, the Diana ChemoClave Transfer Set carries the same intended use as the predicate in accordance with the FDA's guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]", dated 28 July 2014.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE		
	Subject Device	Predicate (K170110)
Feature	Diana ChemoClave Transfer Set	Diana ChemoLock Transfer Set
System Components	Syringe Unit	Syringe Unit
	Connector to Sourcing/receiving containers	Connector to Sourcing/receiving containers
	Connection Tubing	Connection Tubing
	Integral stopcock	Integral stopcock
	Cassette Handle	Cassette Handle
Principles of Operation	Multicomponent device compatible with compounding system to distribute fluid from sourcing container to receiving container	Multicomponent device compatible with compounding system to distribute fluid from sourcing container to receiving container
Fluid Transfer Mechanism	Integrated Syringe with connectors - Single Channel	Integrated Syringe with connectors - Single Channel
Closed System	Yes	Yes
Connections to Sourcing/receiving Containers	ChemoClave connector	ChemoLock connector
Pyrogenicity	Non-pyrogenic	Non-pyrogenic
CSTD Scientific Methods and Performance Testing	Microbial Ingress Test Dry Connection Test Positive Pressure Leakage Test Hazardous Drug Exposure Test Emission Test Fluid Flow Chemical Compatibility Stopcock Handle Torque Component Bond Strength Testing Visual Inspection Accuracy Testing Internal Seal Integrity	Microbial Ingress Test Dry Connection Test Positive Pressure Leakage Test Hazardous Drug Exposure Test Emission Test Fluid Flow Chemical Compatibility Stopcock Handle Torque Component Bond Strength Testing Visual Inspection Accuracy Testing Internal Seal Integrity
Biocompatibility	Per FDA Guidance and ISO 10993-1 Biological Effect <ul style="list-style-type: none"> • Hemocompatibility • Cytotoxicity • Sensitization • Intracutaneous Irritation • Acute Systemic Toxicity • Pyrogenicity 	Per FDA Guidance and ISO 10993-1 Biological Effect <ul style="list-style-type: none"> • Hemocompatibility • Cytotoxicity • Sensitization • Intracutaneous Irritation • Acute Systemic Toxicity • Pyrogenicity
Sterilization Method	Radiation (E-beam)	Radiation (E-beam)
SAL	10 ⁻⁶	10 ⁻⁶

The technological differences between the Diana ChemoClave Transfer Set and the predicate is the Use ChemoClave as the closed connector to sourcing and receiving containers to form a closed system as compared to ChemoLock closed connector within the predicate. The difference in technology does not raise different questions of safety or effectiveness.

VIII. Performance Data Functional Testing

Functional testing was conducted to demonstrate the functionality of the Diana ChemoClave Transfer Set that consists of ChemoClave, stopcock, tubing, syringe, and cassette handle. This testing follows the FDA guidance document of "Intravascular Administration Sets Premarket Notification Submissions [510(k)]". Functional Testing included:

- Fluid Flow
- Positive Pressure Leakage
- Chemical Compatibility
- Stopcock Handle Torque
- Component Bond Strength Testing
- Visual Inspection
- Accuracy Testing
- Internal Seal Integrity

Packaging Integrity and Shelf Life

Package integrity and Shelf Life was conducted according to FDA recognized consensus standards of ASTM D4169 Standard Practice For Performance Testing Of Shipping Containers And Systems, ASTM F1980 Standard Guide For Accelerated Aging Of Sterile Barrier Systems For Medical Devices, ASTM F2096 Standard Test Method For Detecting Gross Leaks In Packaging By Internal Pressurization (Bubble Test), and ASTM F88 Standard Test Method For Seal Strength Of Flexible Barrier Materials.

Biocompatibility

The biocompatibility evaluation for Diana ChemoClave Transfer Set was conducted in accordance with the FDA Guidance for Industry and FDA Staff - "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process'", June 16, 2016; and ISO 10993-1 "Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process", as recognized by FDA. Testing included:

- Hemocompatibility
- Cytotoxicity
- Sensitization
- Intracutaneous Irritation
- Acute Systemic Toxicity
- Pyrogenicity

Microbial Ingress Testing

Microbial ingress testing was conducted to demonstrate that needless access site of Diana ChemoClave Transfer Set maintains physical integrity and mechanically prohibits the transfer of environmental contaminants into the system in use after access (the device is intended for single use). The tests were conducted consistent with the recommendations for microbial ingress testing provided in FDA guidance titled "*Intravascular Administration Sets Premarket Notification Submissions [510(k)]*" issued on July 11, 2008.

Emission, Dry Disconnection, and CSTD Hazardous Drug Exposure Evaluation

Emission, Dry Disconnection, and CSTD Hazardous Drug Exposure Evaluation were performed to validate no escape of drug from the subject device outside the closed system.

Particulates

Particulate contamination testing was performed by following USP <788> to demonstrate particulate levels in the subject device meet USP 788 requirements.

Sterility Testing

E-beam sterilization process validation was conducted according to ISO 11137-1 and ISO11137-2, Sterilization of health care products – Radiation: Requirements for development, validation and routine control of a sterilization process for medical devices. Bacterial endotoxin testing was conducted based on AAMI ST72 and USP <85>, and followed FDA Guidance for Industry – Pyrogen and Endotoxins Testing: Questions and Answers.

IX. CONCLUSION

The Diana ChemoClave Transfer Set meets the functional claims and intended use as described in the product labeling. The Diana ChemoClave Transfer Set is substantially equivalent to the predicate device.